# REMARKS

Claims 16-63 are currently pending in this application. In the Office Action mailed March 5, 2009 ("Office Action"), claims 16-63 were rejected. No amendments have been made to the claims and no new matter is added through this response. Applicants respectfully request reconsideration and allowance of the claims in light of the following remarks.

The Office Action summary indicated that each of the pending claims 61-63 were rejected. However, the Applicants note that no rejections were set forth with regard to claims 54-59. Claims 54-59 are believed to contain allowable subject matter and an indication of allowability is respectfully requested.

## Specification

The specification and amendments thereto submitted on November 14, 2008 were objected to as the Examiner could not find support for the two additional paragraphs (added by the amendment) within the applications PCT/US02/22247, PCT/US02/30617, and PCT/US03/02056, which were incorporated by reference at the time of filing. The Examiner asked the Applicants for location (e.g. page and paragraph no.) in the above identified applications that provides support for the addition of the two new paragraphs.

The Applicants direct the Examiner's attention first to PCT/US02/22247 (referenced to the corresponding International Publication WO 03/005887). Specific support for the amendments added to the specification may be found in the paragraph beginning on pg. 8, the paragraph on pg. 12, ln.12-20, and the paragraph beginning on pg. 14, ln. 23 and ending on pg. 15, ln. 6. Applicants respectfully submit that the referenced paragraphs fully support the requested amendments. For further support, Applicants direct the Examiner to the paragraph beginning on pg. 19, ln. 25 and ending on page 20, ln. 21 and the paragraph beginning on page 22, ln. 26 and ending on page 23, ln. 6 of PCT/US02/30617 (referenced to the corresponding International Publication WO 03/026482). Still additional support may be found in paragraphs [0069]-[0070] and [0082]-[0083] of PCT/US03/02056 (referenced to the corresponding International Publication WO 04/064634). Because the subject matter added to the specification was contained within at least one of the references noted above, which were properly incorporated by reference at the time of filing, no new matter was added via the amendment to the specification. The Applicants respectfully request favorable recognition and acceptance of the amended specification in light of the above information.

### Claim Rejections - 35 U.S.C. 112, first paragraph

Claims 61-63

Claims 61-63 were rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement. Specifically, the Examiner argues that the specification (submitted on October 8, 2003 and November 14, 2008) does not describe “determining at least one of nerve proximity and nerve direction includes determining a threshold stimulation level required to evoke said neuromuscular response,” or that the “step of determining a threshold stimulation level includes establishing first a bracket containing said threshold stimulation level and bisecting said bracket to form a smaller second bracket containing said threshold stimulation level.” The Applicants respectfully disagree. With respect to the first element, the first paragraph added to the specification on November 14, 2008 states that “the surgical access system detects the presence of (and optionally, the distance and/or direction to) nerves by determining a stimulation current threshold level (“$I_{thresh}$”) required to evoke a predetermined neuromuscular response (e.g. an EMG response of 100μV),” and further that $I_{thresh}$ may “provide the user (by way of example only) with an indication of proximity.” With respect to the second element, the second paragraph added to the specification on November 14, 2008 not only indicates that $I_{thresh}$ (i.e. threshold stimulation level) may be determined by establishing first a bracket containing said threshold stimulation level and bisecting said bracket to form a smaller second bracket containing said threshold stimulation level, but also provides a detailed example of how the bracketing and bisection methods are utilized to determine $I_{thresh}$.

As discussed above, the subject matter added with the addition of the new paragraphs on November 14, 2008 was properly incorporated by reference at the time of filing and, as such, does not constitute new matter. Furthermore, the subject matter is presented in the specification in such a way that a person of skill in the art would be reasonably apprised that the Applicants were in possession of the claimed invention and enabled to make and/or use the invention. Applicants respectfully request withdrawal of the rejection under 35 USC 112 in favor of an indication of the allowability of claims 61-63.

## Claim Rejections - 35 U.S.C. 103(a)

### Claims 16-21, 23-51, 53 and 60

Independent claims 16, 31, 46 and particular dependent claims were rejected under 35 USC 103(a) as being unpatentable by US Patent 5,728,046 to Mayer et al. ("Mayer") in view of US Patent Publication US 2005/0075578 to Gharib et al. ("Gharib"). Applicants respectfully submit that even if a person of skill in the art would have been prompted to modify the retractor and methods of Mayer as proposed (an issue that is not conceded herein), the proposed combination of Mayer and Gharib would nevertheless fail to disclose all the elements of claims 16, 31, and 46.

Significantly, the invention of claims 16, 31, and 46 describes using a retractor assembly that may be used to create a minimally invasive operative corridor to the spine via a lateral trans-psoas approach. Doing so requires that care be taken to avoid contacting or impinging nerves that exit the spinal canal and traverse through the posterior portions of the psoas muscle. By fixing the first retractor blade to a posterior aspect of the spinal target site and moving the second retractor blade relative to the first retractor blade, tissue is moved generally away from the posterior lying nerves of the psoas, alleviating the risk of impinging nerves through movement of the blades and expansion of the operative corridor.

Unlike claims 16, 31, and 46, Mayer does not disclose a method of establishing an operative corridor by "**fixing a first retractor blade introduced by a lateral, trans-psoas approach** such that the first blade is **positioned along a posterior aspect of said spinal target** site." Nor does Mayer teach moving a second retractor blade "introduced to said spinal target site via a lateral, trans-psoas approach" relative to said affixed first retractor blade, such that an operative corridor is established." Instead, Mayer teaches introducing a retractor assembly through an anterior approach and fixing each of two opposing blades to anterior portions of the adjacent vertebral bodies. Specifically, "two bone screws 36 are first screwed with their extensions 35 into the patient's bone," and then the retractor "is then lowered from above onto the extensions 35." (Mayer at col. 3 ln.43-53). The failure of Mayer to teach at least positing the first retractor blade along a posterior aspect of the of the spinal target site via a lateral trans-psoas approach was recognized by the Examiner on page 4 of the Office Action.

Gharib does not overcome the voids in the teachings of Mayer. The Office Action suggests that Gharib teaches "a first retractor blade, fig. 2, element 62 introduced to the spinal target site via a lateral trans-psoas approach where the retractor blade is positioned along a posterior aspect of the spinal target site." Applicants respectfully disagree. While Gharib does teach accessing the spine via a lateral trans-psoas approach with the k-wire and cannulas 48-50 (described in para. 62), the element 62 (described in para. 64) is neither a "retractor blade" according to claims 16, 31, and 46, nor is it utilized through the lateral approach.

Gharib describes a neurophysiological system that may be used during various surgical procedures to monitor and prevent damage to nerves. In paragraph 62 Gharib teaches one such use, that of accessing the spine through a lateral trans-psoas approach. In particular, Gharib teaches an access system 34 including a series of dilators which is disclosed as being "particularly suited for establishing an operative corridor to an intervertebral target site in a posterolateral, trans-psoas fashion so as to avoid the bony posterior elements of the spinal column." (Gharib at para. 62). On the other hand, para. 64 of Gharib describes a different use for the neurophysiology monitoring of Gharib using different instrumentation. In para. 64 Gharib describes a nerve root retractor 62 that is typically used during open posterior access procedures where the nerves are visualized and then the retractor is "introduced into or near a surgical target site in order to hook and retract a given nerve [root] out of the way." By monitoring the retraction neurophysiologically, Gharib seeks to avoid damage to the nerve root from over or prolonged retraction during, for example, a posterior lumbar discectomy, decompression, PLIF, TLIF, etc… Thus, the nerve root retractor 62 is not "introduced to the spinal target site via a lateral trans-psoas approach" as suggested by the Office Action. Furthermore, the nerve root retractor 62 is used to move a nerve after the patients back tissue has been retracted out of the way to access the spine and form the operative corridor, as opposed to the invention of claims 16, 31, and 46, where movement of the retractor blades relative to each other forms the operative corridor.

Significantly, the invention of claims 16, 31, and 46 describes using a retractor assembly that may be used to create a minimally invasive operative corridor to the spine via a lateral trans-psoas approach. Doing so requires that care be taken to avoid contacting or impinging nerves that exit the spinal canal and traverse through the posterior portions of the psoas muscle. By fixing the first retractor blade to a posterior aspect of the spinal target site and moving the second retractor blade relative to the first retractor blade, tissue is moved generally away from the posterior lying nerves of the psoas, alleviating the risk of impinging nerves through movement of the blades and expansion of the operative corridor. Mayer Since Mayer fixes bone screws to the vertebrae and forms the operative corridor relative to the fixed bone screws using the retractor assembly, Mayer does not prevent tissue from being pushed posteriorly and causing impingement on the exposed nerves which travel alongside and out from the spine.

Since Mayer and Gharib are both silent with regard to at least one common element of claims 16, 31, and 46, the Applicants submit that one of skill in the art would not have been led to the invention of claims 16, 31, and 46 when considering, whether alone or in combination, the Mayer and Gharib references. Applicants submit that claims 16, 31, and 46 are patentable over Mayer, Gharib, and all other references cited in the record. Furthermore, claims 17-21, 23-30, 32-45, 47-51, 53, and 60 depend from and are further limiting of claims 16, 31, and 46 and they are patentable at least for the reasons set forth with regard to the patentability of claims 16, 31, and 46, as well as the additional limitations they contain. Prompt allowance of claims 16-63 is respectfully requested.

## Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. The Applicant hereby authorizes a payment of the $245.00 fee for the 2 month Extension of Time and the $180.00 fee for filing an IDS to be charged to Deposit

Account No.: 50-2040 for Customer No.: 30,328. No other fees are deemed necessary at this time, however, if necessary, please apply any charges or credits to Deposit Account No.: 50-2040 for Customer No.: 30,328. In the event that there are any questions concerning this amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

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